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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,750	09/23/2003	Victor E. Kimball	11242/320	1782

34205 7590 11/17/2005

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EXAMINER

NASSER, ROBERT L

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/668,750	Applicant(s) KIMBALL ET AL	
	Examiner Robert L. Nasser	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/29/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election without traverse of Species I, claims 1-38 in the reply filed on 8/26/2005 is acknowledged.

Claim Objections

Claim 1 is objected to in that there is no antecedent basis for the sensor means in line 5.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 34 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 34 is rejected in that it recites a positive relationship to the human body. The human body is non-statutory subject matter and cannot be positively recited. Applicant should amend the claim to recite that the holder is adapted to support the tongue.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-29, 33-35, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg et al 4538618, or in the alternative under 103(a) as being unpatentable over by Rosenberg et al. With respect to claim 1, Rosenberg has a blood flow sensor, i.e. fiber 16, located in a measuring head 2 and an indicator 36, for indicating the blood flow measurement. The device further includes a PCO2 sensor (see column 5, line 55). It is the examiners position that there would also be an indicator for indicating the PCO2 measurement, given that the reference provides an indicator for all of the other measured values. Alternatively, the examiner takes official notice that it is well known to display measurement values in medical devices, to inform the user and/or the physician of the patient's condition. The examiner notes that the degree of systemic perfusion could then be deduced from the indicator. Claims 2-21 are rejected in that the device is capable of being positioned adjacent any of the mucosal surfaces recited. With respect to claims 23-27, the examiner notes that the positioning means recited in the specification is a structure that holds the sensor in place when in use. However, the "positioning" function is an intended use limitation. In order to meet the claim language, the reference need only have a structure that is

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capable of performing that function. In Rosenberg, element 4 or element 26 both are devices that are capable of being used to hold the sensor in position adjacent a mucosal surface. As such, Rosenberg meets the intended function of the positioning means and meets the claim limitation. With respect to claims 28 and 29, the flow sensor is laser-doppler or ultrasonic (see column 5, lines 43-50). Claims 33-35 are rejected in that in addition to the features discussed above, the sensor holder is "shaped" to fit under the tongue and support the tongue, and includes a back surface, or "slot" that is capable of receiving the frenulum. The examiner notes that the phrase "shaped to fit" is being interpreted as meaning only capable of fitting. The examiner suggests that applicant recite that the sensor holder has a shape corresponding to the shape of the area under the tongue or use similar language. Claim 38 is rejected for the reasons given above.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al in view of Riccitelli et al 5166990. Riccitelli et al further teaches that it is known to monitor pH and PCO₂ in the same intravascular measuring device. As such, it would have been obvious to modify Rosenberg to include a pH sensor, to provide a more complete picture of the patient's condition.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al in view of Boggett et al WO 98/20794. Boggett et al further teaches that in a microvascular monitoring device like that of Rosenberg, that it is known to monitor the rate of change of blood flow. As such, it would have been obvious

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to modify Rosenberg to include a rate of change of flow determining device, to provide a more complete picture of the patient's condition.

Claims 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Millar 4966148. Millar shows a device including a blood flow sensor and a sensor holder 20 that is capable of holding the device in place, as discussed with respect to Rosenberg above. Millar does not state that it has an indicator. However, the examiner takes official notice that it is well known to display measurement values in medical devices, to inform the user and/or the physician of the patient's condition. The examiner notes that the degree of systemic perfusion could then be deduced from the indicator. With respect to claim 37, Millar teaches a device with a flow sensor and a pH sensor (see column 2, lines 28-49). Again, it would have been obvious to include the indicator, as discussed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
November 12, 2005



ROBERT L. NASSER
PRIMARY EXAMINER